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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,066	12/07/2001	David A. Schwartz	875.010US2	2746
21186	7590	11/03/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			EXAMINER MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,066	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Joseph F. Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/10/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 28 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 28, 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

Claims 17-19, 28, 32-40 are pending and under consideration.

Response to Amendment

Applicant's arguments filed 8/10/2005 have been fully considered but they are persuasive in part.

The rejection of claims 17-19, 28, 32-40 under 35 USC 103(a) has been withdrawn based on Applicant's amendment.

New issues necessitated by Applicant's amendment are set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19, 28, 32-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for A method to detect a polymorphism in a human TLR4 gene, comprising: detecting or determining whether amplified TLR4 DNA obtained from a human nucleic acid sample comprises nucleic acid encoding TLR4 polypeptide having an amino acid substitution at residue 299 or 399 of TLR4, wherein the amplified TLR4 DNA is obtained by contacting an amount of the nucleic acid sample with an amount of at least one TLR4-specific oligonucleotides under conditions effective to simplify TLR4 DNA having SEQ ID NO: 62, the complement thereof, or a portion thereof, and wherein the TLR4-specific oligonucleotides comprises at least two nucleotide substitutions which result in a restriction site that is indicative

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of a polymorphism in a human TLR4 gene at residue 299 or 399, does not reasonably provide enablement for a method to detect a polymorphism in a human TLR4 gene, comprising: detecting or determining whether amplified TLR4 DNA obtained from a human nucleic acid sample comprises nucleic acid encoding TLR4 polypeptide having an amino acid substitution at residue 299 or 399 of TLR4, wherein the amplified TLR4 DNA is obtained by contacting an amount of the nucleic acid sample with an amount of at least one TLR4-specific oligonucleotides under conditions effective to simplify TLR4 DNA having SEQ ID NO: 62, the complement thereof, or a portion thereof, and wherein the TLR4-specific oligonucleotides comprises at least two nucleotide substitutions which result in a restriction site that is indicative of a polymorphism in a human TLR4 gene that encodes a TLR4 polypeptide with an amino acid substitution at residue 299 or 399. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is not clear from the claims as written that the TLR4 oligonucleotides will specifically bind the polymorphisms encoding the amino acid substitution at position 299 or 399. As written, the claims read on methods using oligos that bind elsewhere in the TLR4 gene sequence indicating other polymorphisms. The specification discloses the polymorphisms that encode the 299 and 399 substitutions, not any other polymorphisms in the TLR4 gene. It would require undue experimentation to determine whether there were other polymorphisms, and whether these other possible polymorphisms were indicative of any disease state (see ¶117 and ¶119). Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the other possible TLR4 polymorphisms. Since detailed information

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regarding the structural and functional requirements of the other polymorphisms are lacking, it is unpredictable as to which other polymorphisms, if any, meet the limitations of the claims.

Due to the large quantity of experimentation necessary to determine whether there were other polymorphisms, and whether these other possible polymorphisms were indicative of any disease state, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope. This rejection was necessitated by the addition of the term “a polymorphism in a human TLR4 gene” to claim 28 in the reply filed 8/10/2005.

Conclusion

Claims 17-19, 28, 32-40 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Primary Examiner
Art Unit 1646
October 19, 2005



**JOSEPH MURPHY
PATENT EXAMINER**